MAR 14 2012

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Name of Submitter, Contact Person and Date Summary Prepared:

Name:	Vital Signs, Inc., a GE Healthcare Company
Address:	20 Campus Rd. Totowa, NJ 07512
Official Contact:	Stacie Geffner-Atiya Regulatory Affairs Manager
Phone: Fax:	973-956-5491 973-956-5442
Alternate Contact:	Agata Smieja 410-456-0329
Date of Preparation:	September 30, 2011

2. Device Trade Name and Common Name:

Trade Name:	enFlow IV Fluid Warmer
Common/Usual Name: Classification Name:	Sterile Fluid Path, in-line Blood Fluid Warmer Warmer, Thermal, Infusion Fluid Warmer Blood, Non Electromagnetic Radiation

3. Product Code: LGZ
BSB – 21 CFR 864.9205

Device Class: Class II

4. Legally Marketed Predicate Device:

Substantial equivalence is claimed to:
Enginivity / Vital Signs eFlow Model 100 IV Fluid Warmer (K060537)

5. Description of the Device:

The Vital Signs, Inc. enFlow IV Fluid Warmer consists of a Warmer, Controller (Power Supply) and single use sterile disposable cartridges, which are available with or without an IV tube extension set. The warmer will deliver infuscate to a patient at a temperature of up to 40°C at flow rates of 1 ml/min to a maximum of 200 ml/min.

The sterile disposable cartridges consist of a plastic housing and biocompatible coated aluminum extrusion which when combined form an enclosed fluid path. Heat, generated by electrical resistance, is transferred from the warmer to the fluid through the extrusion. Standard Luer fittings at the input and output allow the connection of standard hospital IV lines to the enclosed fluid path. The Controller serves as the power supply for the Warmer unit.

6. Intended Use of the Device:

The enFlow IV Fluid Warmer is indicated for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.

7. Technology:

The Vital Signs, Inc. enFlow® Fluid Warmer is substantially equivalent to the previously cleared eFlow IV Fluid Warmer (K060537). The basis for this submission is to notify the FDA of the accumulation of various modifications to the enFlow IV Fluid Warmer since the previous clearance, including minor labeling, shelf life, design and software modifications. There have been no changes to the fundamental scientific technology of the device.

8. Discussion of Non-clinical Studies:

The following quality assurance and design control measures were applied to the development of the enFlow IV Fluid Warming system and, as described within the 510(k) notification, support the substantial equivalence of the device:

- Risk Analysis
- Requirements Development and Reviews
- Software Verification and Validation
- Performance/Functional Verification and Validation
- Biocompatibility Testing
- Sterilization and Shelf Life Testing
- Electrical Safety and EMC Testing

9. Summary of Clinical Tests:

The modifications made to the enFlow IV Fluid Warmer did not require clinical testing to support substantial equivalence.

10. Conclusion:

Vital Signs, a GE Healthcare Company, considers the enFlow IV Fluid Warmer to be as safe, as effective, and the performance to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Stacie Geffner-Atiya
Regulatory Affairs Manager
Vital Signs, Incorporated
20 Campus Road
Totowa, New Jersey 07512

MAR 1 4 2012

Re: K112902
Trade/Device Name: enFlow IV Fluid Warmer
Regulation Number: 21 CFR 864.9205
Regulation Name: Blood and Plasma Warming Device
Regulatory Class: II
Product Code: LGZ
Dated: February 16, 2012
Received: February 17, 2012

Dear Ms. Geffner-Atiya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: **enFlow IV Fluid Warmer**

Indications for Use:

The enFlow IV Fluid Warmer is indicated for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.

Prescription Use_____✔_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/8/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112902